



OCT 5 - 2004

120 42232

510(k) Summary

807.92(c)

1 Submitter Information:

807.92(a)(1)

1.1 Submitter:

Codonics, Inc.
17991 Englewood Drive
Middleburg Heights, Ohio 44130

1.2 Manufacturing Facility:

Same as above

1.3 Representative:

Not applicable at this time

1.4 Contact:

Alan DeSantis, Phone:(440) 243-1198 / Fax : (440) 243-1334
17991 Englewood Drive
Middleburg Heights, Ohio 44130

1.5 Date: August 13, 2004

2 Device Name

807.92(a)(2) & 807.92(a)(3)

2.1 Camera, Multiformat, Radiological

2.2 Classification Name: Medical Image Hardcopy Devices

Classification Number: 892.2040

2.3 Classification Code: LMC

2.4 Trade/Proprietary Name: NP-2600 Series Medical Dry Imagers

2.5 Predicate Devices:

Codonics NP-1660 Series Medical Printers (Premarket notification K003481), Codonics Horizon Series Medical Hardcopy Dry Imagers (Premarket notification K021054), Codonics EP-1000 Medical Image Hardcopy Color Printers (premarket notification K030690) and the Seiko ColorPoint 1720 (Premarket notification K991282)

3 Device Description

807.92(a)(4)

3.1 Function

The NP-2600 Series Imagers are dry, thermal, color-only (NP-2600), grayscale only (NP-26xx) and grayscale/color(NP-2660) printer/imagers. The devices produce continuous tone, diagnostic quality B/W images on transmissive film and reflective incident-light-viewed media. The color images produced via dye-diffusion technology are photographic quality implementing a "CRT to Image" matching process for medical applications.

3.2 Scientific Concepts:

Digital images, input directly or via Local Area Network, are managed via communication standards including however not limited to FTP, TCP/IP, and DICOM. Images of a variety of digital formats are managed via industry standard format conversion software and image rendering algorithms including however not limited to TIFF, GIF, PCX, BMP, PBM, PGM, PPM, XWD, JPEG, SunRaster, SGI, Targa, DICOM, DEFF, and Postscript. Interpolation and scaling of images without Lossy data compression is employed in this device to maintain data integrity. Validated digital linear and visual linear routines and verified industry/modality specific Look Up Tables (LUTs) are applied to optimize color and CRT image hardcopy display results.

Imaging is accomplished via directly-modulated discrete-element thin-layer linear thermal print head technology. The recording medium is either heat sensitive silver in the case of grey scale film, heat activated dye in the case of DirectVista[®] reflective record imaging, or thermal heat activated dye-diffusion from a color donor in the case of ChromaVista[®] reflective or transmissive color imaging. The action of heat on the grey scale media produces a black dye in the medium. The action of heat on the dye-diffusion media produces a precision mixing of colors, which diffuse into the medium's top layer. The image formation is accomplished without wet chemistry processing common to many laser film imaging systems in use today.

3.3 Physical And Performance Characteristics:

In the case of medical image hard copy devices, important performance characteristics, which affect the effectiveness and safety, relate to the fidelity of the modulation transfer function. Spatial frequency response, grey scale resolution, density response and full image field uniformity combine to affect the final image. Characteristic response of thermal print head and film response must be mapped and compensated for to achieve suitable performance.

Pixel size (81 μ for the NP-2600 Series Imagers) produces a pixel resolution of 12.4 pixels/mm or 314 dpi. The grey scale resolution produces a palate of 256 levels of discernable grey, while the color palate produces 256 levels each of yellow, magenta and cyan for a total of 16.7 million colors. The SMPTE resolution and contrast pattern and uniform density response function confirms quality suitable for the intended medical imaging use.

4 Device Intended Use: 807.92(a)(5)

- 4.1 The intended uses of the NP-2600 Series Imagers is high resolution hard copy imaging of digital image source material and through the conversion of electronic signals from a wide variety of direct/indirect medical imaging modality outputs. The hardcopy output includes however is not limited to, digital radiography, nuclear medicine, ultrasound, CT, MRI, CR and Radiation Therapy planning. Images are suitable for medical image diagnosis use and referral. The system is intended for use by medical radiologists, imaging modality specialists, and communications to referring physicians.
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5 Device Technological Characteristics: 807.92(a)(6)

5.1 The characteristics of the NP-2600 Series Imagers compare substantially to the Codonics NP-1660 Series Medical Printers (Premarket notification K003481), the Codonics Horizon® Ci Medical Imager (Premarket notification K021054), the Codonics EP-1000 Medical Image Hardcopy Color Printers (Premarket notification K030690) with respect to color, reflective media printing, and Seiko ColorPoint 1720 (Premarket notification K991282) in system function and intended uses. The technology and applications are substantially equivalent to models of printers already cleared to market by the FDA. Differences of note do not affect safety and effectiveness of the device, intended use, or application methods. The device operates in a manner substantially equivalent to other cleared devices in this category.

6 Testing and Equivalence: 807.92(b)(1), 807.92(b)(2) & 807.92(b)(3)

6.1 In the code implementation, electrical compliance tests, simulation, printer resolution pattern testing, and clinical studies, results and outcomes will be thoroughly reviewed with proper operation and intended functions verified. The device will pass a series of electrical safety tests including UL 2601-1, CAN/CSA-C22.2 No 601.1-M90, IEC EN-60601-1. The devices will comply with electromagnetic standards defined in EN-60601-1-2 (2001). Laboratory tests have documented effective application and expected results consistent with predicate devices currently in commercial distribution and additional verification and validation testing is planned prior to release.

Codonics believes the NP-2600 Series Imagers to be substantially equivalent to Medical Image Hardcopy Devices currently in commercial distribution in the U.S. We have selected the Codonics NP-1660 Series Medical Printers (Premarket notification K003481), Codonics Horizon Series Medical Hardcopy Dry Imagers (Premarket notification K021054), Codonics EP-1000 Medical Image Hardcopy Color Printers (premarket notification K030690) and the Seiko ColorPoint 1720 (Premarket notification K991282) as the predicate devices for our claim of substantial equivalence, Attachment 6 contains information describing these predicate devices and provides a comparison of the NP-2660 Series Imagers to the predicate device(s) and describes how any differences of note are substantially equivalent.

7 Hazard Analysis and Safety Concerns

7.1 Hazard analysis on this product has been performed throughout the product concept and testing phases of the product development and implementation. This process has emphasized:

- Identification of potential hazards, their causes and their effects
- Development of methodologies to control the occurrence of hazards and to constrain their effects;
- Determine any effect on patient safety and system effectiveness

The potential hazards associated with this product are not different than those of other hardcopy image components. These are primarily related to the failure of computer system components, and may be variously obviated by decisions taken by the end users of the product. None of the failures are expected to materially contribute to patient death or injury.

It is our conclusion that no hardware or software component, operating in a properly configured environment, whose latent design defect would be expected to result in death or injury of the patient. Thus the "level of Concern" is "Minor".



OCT 5 - 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Alan DeSantis
Director of Quality and Regulatory Affairs
Codonics, Inc.
17991 Englewood Drive
MIDDLEBURG HEIGHTS OH 44130

Re: K042232
Trade/Device Name: NP-2600 Series
Hardcopy Printers
Regulation Number: 21 CFR 892.2040
Regulation Name: Medical image
hardcopy device
Regulatory Class: II
Product Code: 90 LMC
Dated: August 13, 2004
Received: August 20, 2004

Dear Mr. DeSantis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

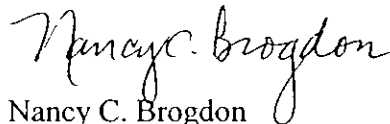
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K042232

Device Name: NP-2600 Series Hardcopy Printers

Models: NP-2660 Medical Color, Grayscale and Film Dry Imager
NP-2600 Medical Color Dry Imager
NP-26xx Medical Grayscale Reflective and/or Film Dry Imager
(exact model number to be determined)

Indications For Use:

The intended uses of the NP-2600 Series Imagers is high resolution hard copy imaging of digital image source material and through the conversion of electronic signals from a wide variety of direct/indirect medical imaging modality outputs. The hardcopy output includes however is not limited to, digital radiography, nuclear medicine, ultrasound, CT, MRI, CR and Radiation Therapy planning; however, does not include digital mammography hardcopy. Images are suitable for medical image diagnosis use and referral. The system is intended for use by medical radiologists, imaging modality specialists, and communications to referring physicians.

The intended uses are essentially identical to the Codonics NP-1660 Series Medical Printers (Premarket notification K003481), the Codonics Horizon Series Medical Hardcopy Dry Imagers (Premarket notification K021054). The intended uses are identical to the Codonics EP-1000 Medical Image Hardcopy Color Printers (Premarket notification K030690) and the Seiko ColorPoint 1720 (Premarket notification K991282) in terms of color, reflective media output.

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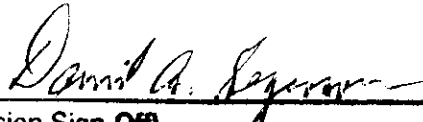
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

(Optional Format 1-2-96)


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042232